IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICALS, INC.,
Plaintiff,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of Centers for Medicare & Medicaid Services; DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND CENTERS FOR MEDICARE & MEDICAID SERVICES,
Defendants.

Case No. 3:23-cv-03818-ZNQ-JBD

BRIEF OF ECONOMISTS AND SCHOLARS OF HEALTH POLICY AS AMICI CURIAE IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

JAMES C. SHAH
ALEC J. BERIN
MILLER SHAH LLP
2 Hudson Place
Suite 100
Hoboken, NJ 07030
(866) 540-5505
jcshah@millershah.com

DEEPAK GUPTA
GUPTA WESSLER LLP
2001 K Street, NW
Suite 850 North
Washington, DC 20006
(202) 888-1741
deepak@guptawessler.com

October 23, 2023

Counsel for Amici Curiae

TABLE OF CONTENTS

TABLE OF AUTHORITIES

INTRODUCTION AND INTEREST OF *AMICI CURIAE*[1]

This case concerns the constitutionality of the Inflation Reduction Act's drug-pricing provisions. Amici are economists and health policy scholars who focus their work on healthcare markets and pharmaceutical drug pricing. Because they are not lawyers, they do not directly address the parties' competing constitutional arguments. Instead, they submit this brief to provide the Court with the background necessary to understand the context in which those arguments arise—context concerning the economics of the Medicare market; the relationship between intellectual property rights, drug prices, and innovation; and the Inflation Reduction Act's role in correcting for market failure and restoring bargaining equity. Amici are:

Richard G. Frank
Margaret T. Morris Professor of Health Economics Emeritus,
Harvard Medical School;
Leonard D. Schaeffer Chair in Economic Studies,
The Brookings Institution

Fiona M. Scott Morton
Theodore Nierenberg Professor of Economics,
Yale School of Management

Aaron S. Kesselheim
Professor of Medicine,
Brigham and Women's Hospital/Harvard Medical School

Gerard F. Anderson
Professor of Health Policy & Management,
Johns Hopkins University Bloomberg School Public Health;
Professor of Medicine,
Johns Hopkins University School of Medicine

Rena M. Conti
Associated Professor,
Questrom Business School, Boston University

---

[1] No party opposes the filing of this brief. No party or counsel for a party—nor any person other than amici and their counsel—authored this brief in whole or in part or contributed any money intended to fund its preparation or submission.

David M. Cutler
Otto Eckstein Professor of Applied Economics
Harvard University

Jack Hoadley
Research Professor Emeritus,
Health Policy Institute, McCourt School of Public Policy, Georgetown University

Janssen's motion for summary judgment asserts (at 1, 32) that the Inflation Reduction Act's Negotiation Program "unliterally impose[s] punitive price controls" and "is specifically designed to impose unfair prices." This brief shows how Janssen's contention reflects an overly simplistic and misleading account of the prescription-drug market.

The market for prescription drugs does not function like other markets. In the bread market, for example, there are no laws that prevent direct competition among sellers to skew prices and demand. Consumers can decide which bread they prefer to purchase, based on taste, ingredients, price, and other characteristics, and which bakery to buy from. A bakery must set its prices to satisfy consumers and meet its competition. In the drug market, however, the relationship between sellers and consumers is not as unfettered. To provide a period of guaranteed revenue that recoups investment in drug development, the government provides drug companies with patents and several years of exclusivity—making a particular drug the only available product of that specific formulation for *at least* 5 years, and for 12–14 years on average. During that time, drug companies use their market power to set prices well above the costs of production and distribution. Far from reflecting the "true value" of the drug, the prices set during these periods reflect the market exclusivity under which drug manufacturers operate.[2] This forces payors like Medicare to pay exorbitant prices for brand-name drugs without generic alternatives.

---

[2] David H. Howard, Rena M. Conti et al., *Pricing in the Market for Anticancer Drugs*, 29 J. Econ. Perspectives 139 (2015).

The Inflation Reduction Act takes several steps to correct course. It gives Medicare the authority to negotiate prices for drugs that have been on the market for at least 9–13 years. By doing so, it provides consumers with enough bargaining power to counter the pharmaceutical monopolist in establishing a price. The harm to true innovation is negligible because any drug eligible for negotiation will almost certainly have already recouped its investment many times over. This brief explains how, contrary to Janssen's contention, the Inflation Reduction Act pushes the drug market's dynamics closer to competitive equilibrium, not further away.

ARGUMENT

I. Tensions between incentives for innovation and consumer protection frame the mechanics of the prescription drug market.

A. The development of prescription drugs is costly and offset by government subsidies.

Research-and-development costs for new prescription drugs are high,[3] because the process to develop a prescription drug is long, and clinical trials are expensive. Research and development usually consists of early-stage basic science and preclinical proof-of-principle animal testing; clinical trials in humans (Phase 1); efficacy testing (Phases 2 & 3); and submission for FDA approval.[4] Early phases have high failure rates. Once a drug is submitted for approval, the chance that it will become a marketable product is greater than 50%.[5]

Although most new drugs are brought to the market by private companies, the federal government underwrites a substantial amount of cost, risk, and uncertainty. This mostly includes

[3] Richard G. Frank & Caitlin Rowley, *Much money to be made from developing drugs that will have negotiated prices*, Bloomberg (Sept. 5, 2023).

[4] Michael Hay et al., *Clinical development success rates for investigational drugs*, 32 Nature Biotech. 1, 40-51 (2014); Chi Heem Wong et al., *Estimation of clinical trial success rates and related parameters*, 20 Biostats. 2, 273-86 (2019); Katarzyna Smietana et al., *Trends in clinical success rates*, 15 Nature Revs. Drug Discovery 6, 379-80 (2017).

[5] Smietana, *Trends in clinical success rates*, at 379-80.

the cost of basic science and animal modeling but can also include proof-of-concept testing and, in rare cases, later stage human clinical trials. The government invests in drug research primarily through the National Institutes of Health. Reviews show that every single drug approved by the FDA from 2010–2016 linked back to NIH-funded research and that 99.4% of drugs approved from 2010–2019 received NIH funding at some point in development.[6] In contrast to private pharmaceutical companies, the federal government generally receives very limited royalties or financial return on these investments.[7] The federal government also assures that brand drugs are safe, effective, and accurately labeled.[8]

Once a drug receives FDA approval, the industry's priority is to maximize profits. The U.S. government aids this effort by providing manufacturers with two types of market exclusivity for new drugs which could otherwise be easily duplicated: patents and exclusivity periods. These measures block direct competition for a period determined by Congress to balance profit for the innovator and access for the people.[9] First, the government grants drug patents to manufacturers. Patents last about 20 years from the date of application. A drug's primary patent is on the underlying active ingredient and is usually obtained well before FDA approval, around the time of drug discovery. But manufacturers can, and do, obtain numerous additional patents on other formulations, uses, and manufacturing methods for an already successful drug. This process can

---

[6] Ekaterina G. Cleary et al., *Contribution of NIH funding to new drug approvals 2010-2016*, 115 Proc. Nat'l Acad. Scis. USA 10, 2329-34 (2018); Ekaterina G. Cleary et al., *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs. the Pharmaceutical Industry, 2010–2019*, 4 JAMA Health F. 4 (2023).

[7] U.S. Gov't Accountability Off., GAO-21-52, *Biomedical Research: NIH Should Public Report More Information about the Licensing of Its Intellectual Property* 2, 7 (2020) (NIH received up to $2 billion in royalties from its contributions to 34 drugs sold from 1991-2019, compared to $36 billion contributed to research in 2018 *alone*).

[8] Jeremy A. Green & Scott H. Podolsky, *Reform, Regulation, and Pharmaceuticals—The Kefauver-Harris Amendments at 50*, 367 N. Eng. J. Med. 16, 1481-83 (2012).

[9] Richard G. Frank & Paul B. Ginsburg, *Pharmaceutical industry profits and research and development*, Brookings (Nov. 17, 2017).

create a thicket of dozens or even hundreds of patents that block generic entry for many years after the initial patent expires.

Other federal statutes provide guaranteed minimum periods of exclusivity by preventing the FDA from approving competing products for a minimum number of years after regulatory approval. Small-molecule drugs, those derived from chemical processes, are protected for at least 5 years; drugs for rare diseases are protected for 7 years; and biologic drugs, those derived from living organisms, are protected for 12 years.[10] During this time, generic versions of a drug cannot be sold, and any profits from use are earned exclusively by the developer.[11] Large companies use various tactics to extend exclusivity periods past the expiration of initial patents—including settling patent challenges by generic firms, delaying patent filing, refusing to provide samples to generic firms, filing pretextual "citizen petitions" against competitors to delay market entry, and evergreening, which occurs when companies patent existing drugs with slight modifications.[12] Many of these tactics have been pursued by the FTC and DOJ as anticompetitive violations of antitrust laws, but the agencies have been unsuccessful in halting these methods entirely.[13] As a result, the exclusivity for new drugs can exceed what Congress intended and has been found to extend anywhere from 7–35 years.[14]

B. The drug market is not structured like other free markets.

Protecting innovation through exclusivity comes at the expense of traditional free-market

---

[10] Favour D. Makurvet, *Biologics vs. small molecules: Drug costs & patient access*, Med. Drug Discovery, Nov. 23, 2020, at 1.

[11] Food & Drug Administration, *Patents & Exclusivity*, FDA/CDER SBIA Chronicles (May 19, 2015).

[12] Fiona M. Scott Morton & Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets* 2 (Brookings Working Paper No. 30, May 2017); Roger Collier, *Drug patents: the evergreening problem*, 185 Can. Med. Ass'n J. 385 (2013).

[13] Morton & Boller, *Enabling Competition in Pharmaceutical Markets*, at 36.

[14] Benjamin Rome, *Market exclusivity length for drugs with new generic of biosimilar competition, 2012-2018*, 109 Clinical Pharmacology & Therapeutics 2, 367-71 (2021).

principles. A free market is one in which prices and demand are set by decentralized buyers and sellers making informed purchasing decisions. Unlike other markets in the United States—in which sellers compete for sales without significant intervention—patents and other exclusivity periods grant temporary monopolies to drug companies. Regulations dictate the terms of distribution and discounts, and the market is further complicated by the presence of insurance coverage.

In a well-functioning market, the price of a product needs to be set at a level that will incentivize people to purchase it. Here, however, insurance coverage insulates consumers from ever seeing the true price of a drug because they only pay a small percentage of the cost, eliminating the drug companies' catalyst to set reasonable prices. Absent a mechanism to reel back such practices, like the Medicare negotiation program, companies can use unfettered market power to hike drug prices far above those that would be palatable to consumers.[15] While such temporary subsidies may help drug companies recuperate their initial investment, they can hardly claim they're permanently entitled to those benefits.

The end of the exclusivity period plays an important role in recalibrating the market and promoting affordability. When a for-profit company markets a socially valuable patented drug, it is given license to "charge higher than competitive prices" as the only available formulation.[16] Once interchangeable products enter the market, competition naturally pushes prices down, making the drug more accessible to consumers.[17] This feature of the prescription-drug market has always been valued by lawmakers, who passed the Hatch-Waxman Act in 1984 to create a streamlined pathway for generic drugs to come to market when patents and exclusivity periods

---

[15] Richard G. Frank & Joseph P. Newhouse, *Should Drug Prices Be Negotiated Under Part D of Medicare? And If So, How?*, 27 Health Affairs 2, 39 (2008).

[16] Morton & Boller, *Enabling Competition in Pharmaceutical Markets*, at 1.

[17] *Id.*

lapse.[18] As state laws encourage the use of lower cost generic drugs, spending on previously patent-protected drugs can often fall by as much as 80% within 24 months.[19] Insurance coverage, like that offered by Medicare Part D, also plays a crucial role in protecting consumers from the growing costs of prescription drugs and demand for pharmaceutical products. Health plans have implemented tiered benefit structures to steer patients and physicians to use generic versions of drugs when possible.[20] These policies reduce costs incurred by consumers, especially because generic drugs are dispensed more than 90% of the time when they are available.[21]

Imagine a hypothetical drug that is worth $100 to many consumers. Because Medicare enrollees are insured—in part because of high drug prices—they pay only 20% of the cost of the drug at the time the consumer buys it. If a consumer is willing to pay $100, the pharmaceutical company will immediately realize that it can raise price up to $500 without losing customers. The government notices this high price because it raises the cost of Medicare and limits funds that can be used for other healthcare needs. After *10 years* of this pricing model, the government uses its new authority to bargain for lower prices (perhaps $300). Janssen effectively claims that any price below $500 violates "free-market principles," and that the only acceptable outcome is for the government to continue paying $500 forever. The economic absurdity of this claim is self-evident.

---

[18] Wendy H. Schacht & John R. Thomas, Cong. Rsch. Serv., R41114, The Hatch-Waxman Act: Over a Quarter Century Later (Mar. 13, 2012).

[19] Yan Song & Douglas Barthold, *The effects of state-level pharmacist regulations on generic substitution of prescription drugs*, 27 Health Econ 1717, 1717-37 (2018). Chana A. Sacks et al., *Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions*, 181 JAMA Internal Med. 1, 16-22 (2021).

[20] Richard G. Frank, *Prescription Drug Prices: Why Do Some Pay More Than Others Do?*, 20 Health Affs. 2, 115-128 (2001).

[21] Cong. Budget Off., *Prescription Drugs: Spending and Prices* 2 (2022).

C. Higher drug prices do not directly correlate with an increase in innovation.

Drug prices aren't the touchstone of innovation that pharmaceutical companies make them out to be. Empirical studies show that, on average, an increase in the expected number of patients and total revenue of a drug cause more investment and more product entry.[22] Newer studies, however, provide insight into exactly what kind of products are entering the market: These studies find that much of the entry is not "innovation," but rather replication or rebranding of existing drugs. While the number of new drugs entering the market increased after the introduction of Medicare Part D, the new drugs were almost entirely in areas with five or more existing therapies, offering little by way of meaningful innovation.[23] A review for FDA approvals from 2007–2017 revealed that only about one-third of the new drugs in that period had "high therapeutic value," or in other words, offered more than a minimal improvement over drugs or other treatments that were already available.[24] Companies also advertise low therapeutic value drugs widely, [25] and low therapeutic value drugs accounted for $19.3 billion in Medicare spending in 2020, 55% of the total amount spent on the top-50 selling drugs.[26] Further, drug companies took existing drugs that were viewed as insufficiently profitable before the creation of Medicare Part D and relaunched them as the drug market grew, while the market overall showed little evidence of increases in patents or

---

[22] Pierre Dubois, Olivier de Mouzon, Fiona M. Scott Morton, et al., *Market Size and Pharmaceutical Innovation* 11 (TSE Working Paper, March 2014); Wesley Yin, *Market Incentives & Pharmaceutical Innovation*, 27 J. Health Econ. 4, 1060-77 (2008).

[23] David Dranove et al., *Pharmaceutical Profits and the Social Value of Innovation* 1, 10 (NBER Working Paper No. 20212, 2014).

[24] Thomas J. Hwang, Aaron S. Kesselheim, et al., *Association between FDA and EMA expedited approval programs and therapeutic value of new medicines: retrospective cohort study*, 371 British Med. J., 1 (2020).

[25] Neeraj G. Patel, Aaron S. Kesselheim, et al., *Therapeutic value of drugs frequently marketed using direct-to-consumer television advertising, 2015-2021*, 6 JAMA Network Open 1, 1-3 (2023).

[26] Alexander C. Eligman, et al., *Added therapeutic benefit of top-selling brand-name drugs in Medicare*, 15 JAMA 1283, 1283-89 (2023).

publications.[27] Much of the present pharmaceutical research-and-development spending is devoted to line extensions; indeed, a study of all FDA approvals of brand name products from 2011–2021 found that only 36% of companies' expenditures were related to new products, with all other spending focused on extensions of existing drug franchises.[28] The rules and structure of the market incentivize this kind of prioritization. The pharmaceutical-market structure focuses attention on those drugs for which profits are highest, with little consideration of their added value or innovative quality. This allows companies to invest in offshoots of drugs that they already know to be profitable, fend off regulation with disincentive defenses, and market themselves as innovators.[29]

II. The Negotiation Program's legislatively-mandated structure is a fair process and is not unique to the Medicare market.

The hallmarks of a fair negotiation process include communication between parties, differences in interests, and alternatives to negotiation.[30] All of these hallmarks are present in the Negotiation Program established by the Inflation Reduction Act. There are various channels of communication available to the two parties, a clear difference in interests, and a number of alternatives or off-ramps if companies choose not to negotiate.

The Negotiation Program, which proposes a statutory limit on prices and conducts negotiation within those limits, mimics the negotiation process employed by the federal government in several areas. One of these areas is the purchase of prescription drugs by federal

[27] Dennis Byrski, et al., *Market Size & Research: Evidence from the Pharmaceutical Industry* 2 (Planck Inst. Rsch. Paper No. 21-16, May 2021).

[28] Richard G. Frank & Kathleen Hannick, *5 things to understand about pharmaceutical R&D*, Brookings (June 2, 2022).

[29] Increased competition and availability of generic drugs could be the answer. A review of pharmaceutical manufacturers with at least one FDA-approved product from 1985–2001 found that the most important predictor of new product introductions was the loss of exclusivity protection on a current product. *See* Stuart J.H. Graham & Matthew John Higgins, *The Impact of Patenting on New Product Introductions in the Pharmaceutical Industry* 29 (April 4, 2007).

[30] Roger Fisher & William Ury, *Getting to Yes: Negotiating Agreement Without Giving In* 20-84 (2d ed. 1991).

agencies like the Departments of Defense and Veterans Affairs. These agencies purchase prescription drugs under the Federal Supply Schedule and the Federal Ceiling Price program, both of which establish prices available to agencies that purchase drugs directly from pharmaceutical companies.[31] The prices paid by agencies are set "through a combination of statutory rules, "negotiation," and "statutory caps," not unlike the process outlined in the Negotiation Program.[32] Prices sets by the Federal Supply Schedule and Federal Ceiling Price program are up to 40% lower than those paid by the federal government under Medicare Part D.[33] Manufacturers offer agencies like the Department of Defense, Department of Veterans Affairs, Bureau of Prisons, and state Medicaid entities additional concessions through negotiation. Those agencies pay prices that average between 31–59% less than the Federal Supply and Federal Ceiling rates, an effective 75% discount on the rates charged to Medicare.[34] Statutory rebate requirements like that those found in the federal Medicaid statute further lower overall cost for state Medicaid programs, which pay 38% less for prescription drugs than the Department of Veterans Affairs.[35] If these provisions and negotiation programs were disallowed, the federal government's expenditures for prescription drugs—for the Department of Defense, Department of Veterans Affairs, and Medicaid alone—would increase by tens of billions each year.

Concerns that the negotiation process is unfair because of low price caps are unfounded. The Inflation Reduction Act sets statutory discounts based on list prices (what companies choose

---

[31] Cong. Budget Off., *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* 1-2 (2021).

[32] *Id.*

[33] *Id.*

[34] *See id.*; Cong. Budget Off., *Prices for Brand-Name Drugs Under Selected Federal Programs* (2005); Office of the Inspector General, *Review of the Federal Bureau of Prisons' Pharmaceutical Drug Costs & Procurement* 26-27 (2020).

[35] Chris Park, *Medicaid Coverage of Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease* (Sept. 15, 2022), https://perma.cc/9M74-REFH.

to charge for the drug) instead of transaction prices (the price actually charged after rebates and discounts). A drug's list price often exceeds its transaction price. For example, the manufacturers of Imbruvica, a type of targeted cancer drug, reported a list price almost 10% higher than its transaction price.[36] While price caps may slightly lower the substantial profit margin of some branded drugs, they do not come close to requiring companies to sell those drugs at a loss.

Furthermore, the Negotiation Program only applies to a small set of drugs sold in the United States, leaving most of industry's revenue entirely unaffected. The drugs selected for negotiation will have already recovered their initial investment many times over—they are products that have been on the market for at least 9–13 years and generated a revenue *surplus* ranging from $14–80 billion. *Infra* at 12. Incentives for the invention of such drugs are clearly not at risk from the Negotiation Program. The fact that these methods of negotiation have been employed in drug markets outside of Medicare for decades without complaint from the industry or any decline in supply should be dispositive.

III. The Inflation Reduction Act restores bargaining equity between manufacturers and consumers while protecting innovation.

The Inflation Reduction Act counters the imbalanced market by permitting the Department of Health and Human Services to select drugs for price negotiation under Medicare. Opponents argue that the provisions decrease incentives for research and development. But the Inflation Reduction Act includes several safeguards to make a significant reduction in innovation unlikely.

For starters, the Inflation Reduction Act limits the drugs that can be considered for price negotiation. To be considered, a product must be a single-source drug that has been on the market

---

[36] Inmaculada Hernandez et al., *Estimated discounts generated by Medicare drug negotiation in 2026*, 29 J. Managed Care 868, 871 (2023).

for at least 9–11 years (depending on whether it is a biological or small-molecule drug).[37] This by no means limits the companies' ability to cover their research-and-development costs and earn a healthy rate of return on their investment. In fact, recent data on the earnings of all ten drugs selected for negotiation by the federal government under the Inflation Reduction Act shows that every single drug has recouped its initial research-and-development costs (including the cost of failed iterations) and generated a surplus revenue of at least $13.7 *billion* since its launch.[38] The Inflation Reduction Act's provisions neither cut the company off from future profits nor shorten the time that it retains exclusivity. Far from the "nuclear winter for innovation" prophesied by pharmaceutical companies, the Act will at a maximum result in a "small chill in their profit margins."[39] The Act also exempts several categories of drugs from the Negotiation Program. The excluded categories include (1) drugs for a single rare disease that might take longer to recuperate initial investment; (2) drugs soon to be subject to biosimilar competition, since the lower price for the negotiated drug will provide an advantage relative to generic competitors and thus deter their entry into the market; (3) drugs from small biotech firms, where those drugs bring in over 80% of the company's Medicare revenue; and (4) plasma-related products, because their prices reflect fluctuating costs (as opposed to up-front research-and-development investment).[40]

In addition to protecting certain new drugs through exclusion, the Inflation Reduction Act leaves in place important opportunities that promote innovation and increase revenues for large and small pharmaceutical companies. It includes no restrictions on launch prices. Further, it adds

---

[37] Meena Seshamani, Ctr. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026* 13 (June 30, 2023).

[38] Frank & Rowley, *Much money to be made from developing drugs that will have negotiated prices*.

[39] *Id.*

[40] Rachel Sachs, Richard G. Frank, et al., *A holistic view of innovation incentives and pharmaceutical policy reform*, 1 Health Affs. Scholar 1, 2 (2023).

provisions that increase demand for drugs and generate new revenues for the industry. Specifically, its cap on out-of-pocket costs for high-cost products—particularly those like insulin—will increase adherence to treatment regimens and likely boost sales. The Act goes one step further for vaccines, eliminating out-of-pocket costs entirely. It also doubles the research-and-development tax credit for small businesses and expands the conditions under which it can be used, which is especially important for innovation since emerging biopharma companies produced two-thirds of all new drugs in 2022.[41] Finally, alongside the Inflation Reduction Act are whole government biotechnology innovation initiatives like ARPA-H, which funds cutting-edge medical research.[42]

The prescription-drug market has favored manufacturer profits for decades. For this reason, Congress has regularly stepped in to mandate lower prices for government buyers. Each of those changes was resisted by industry because shareholders do not wish to diminish their profit. Those objections are understandable. What is not understandable is the contention that the U.S. drug market is not a highly regulated environment in which many aspects of a firm's business are dictated by regulations and consumer interests. Instead of ignoring this environment, the Inflation Reduction Act works within the confines of this highly regulated market to preserve incentives for valuable innovation while protecting consumers from a market-wide overinflation of drug prices.

CONCLUSION

This Court should deny the plaintiff's motion for summary judgment.

Respectfully submitted,

/s/ Deepak Gupta

DEEPAK GUPTA
GUPTA WESSLER LLP
2001 K Street, NW, Suite 850 North
Washington, DC 20006
(202) 888-1741

---

[41] IQVIA, *Global Trends in R&D 2023: Activity, Productivity, and Enablers* (Feb. 15, 2023).

[42] Sachs, *A holistic view of innovation incentives and pharmaceutical policy reform*, at 2.

deepak@guptawessler.com

JAMES C. SHAH
ALEC J. BERIN
MILLER SHAH LLP
2 Hudson Place
Suite 100
Hoboken, NJ 07030
(866) 540-5505
jcshah@millershah.com

October 23, 2023

Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that on October 23, 2023, I electronically filed this foregoing through this Court's CM/ECF system. I understand that notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

/s/ James C. Shah
James C. Shah